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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,658	08/16/2006	Kazuhiko Katou	294828US0PCT	9975

22850 7590 10/11/2011
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ALEXANDRIA, VA 22314

EXAMINER

WELTER, RACHAEL E

ART UNIT	PAPER NUMBER
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1611

NOTIFICATION DATE	DELIVERY MODE
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10/11/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/589,658	Applicant(s) KATOU ET AL.	
	Examiner RACHAEL WELTER	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/6/11.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/19/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/6/11 has been entered.

Claim Status

Claims 1-17 are pending. Claims 14-17 are newly added.

Withdrawn Rejections

The rejection of claims 1, 3-6, 8-9, and 12 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of applicant's amendments.

The rejection of claims 1, 3-6, 8-9, and 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendments.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leusch et al (WO 00/56276) in view of De Sadeleer et al (US Patent No. 5,973,212).

Claims 14-17 are newly appended to this rejection.

Leusch et al teach oral care compositions including tooth pastes, mouth rinses, mouth sprays, chewing gums, and lozenges (abstract). In Example VI of Leusch et al, a composition comprising 10 wt.% erythritol, 0.31 wt.% xanthan gum, 0.45 wt.% carboxymethyl cellulose, and 23.56 wt.% water is taught (pg. 19). Leusch et al further teach that erythritol and other non-cariogenic carbohydrates can be comprised in the composition in an amount of 1-65 wt.% (pg. 3, lines 1-2). Besides sodium carboxymethyl cellulose and xanthan gum, Leusch et al teach additional thickening agents such as carrageenan (pg. 9, lines 1-6). Such thickening agents can be present in an amount of 0.1-15 wt.% and preferably 2-10 wt.% (pg. 9, lines 18-20). Additionally, Leusch et al teach that coolants can be added to its compositions (pg. 10, lines 5-8).

Although the particle size of erythritol in Leusch et al may be the same as claimed, Leusch et al do not explicitly teach erythritol having an average particle size of 200 um or less.

De Sadeleer et al teach erythritol compositions which are useful in tableting, chewing gum, chocolate, crystallized tablets, and fondants (column 2, lines 1-2). The erythritol preferably has a particle size of 10-250 microns (column 2, lines 17-19). According to De Sadeleer et al, the perception of cooling effect by the mouth is dependent upon the particle size of the erythritol crystals and for maximum effect it is

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desirable to use small but integral and non-fragmented crystals in its applications (column 2, lines 56-63).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to use erythritol with the instant particle size in the compositions of Leusch et al. One would have been motivated to do so with a reasonable expectation of success since De Sadeleer et al teach that such particle sizes are preferable in creating a cooling effect and Leusch desires the optional use of coolants in its compositions. Thus, if one desired to provide an oral care composition with a cooling effect, one would be motivated to add erythritol with the instant particle size.

Regarding the new limitations of claims 14-17 (superior cooling sensation, stability, shape, and applicability), it is the examiner's position that these characteristics are intrinsic properties of the composition taught by Leusch et al and De Sadeleer et al because the prior art suggests the same components as the instant application including the erythritol, water, and binders. According to MPEP 2112.02, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Furthermore, regarding the amounts of the components and the equation recited in the instant claims, it is noted that the prior art cited above teaches amounts that either

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encompass or overlap with the amounts recited in the instant claims. Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the amounts of the prior art because methods of determining appropriate component percentages are well-known in the art, and one of skill in the art would have arrived at the appropriate percentages via routine experimentation. Manipulation of relative amounts of formulation components do not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating unexpected results.

Regarding the instant limitations of claims 6-8, wherein the composition has a viscosity at 25°C from 1500-5000 dPas, it is the examiner's position that this would be an intrinsic property of the composition taught by Leusch et al and De Sadeleer et al because the prior art suggests the same components as the instant application including erythritol, water, and binders. See *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Furthermore, as evidenced by the instant specification, a binder content exceeding 3 wt.% has an unduly high viscosity (see paragraph 0014). Since Leusch et al suggest the instant binder amount; it is assumed that the composition of Leusch et al would not have an unduly high viscosity. Moreover, Leusch et al teach various kinds of oral compositions with different viscosities, including toothpaste, mouth sprays, mouth rinses, lozenges, chewing gums, and gels. As such, one would reasonably expect one of these compositions to have a viscosity that overlaps with the instant claims.

Regarding the limitations of claims 13-14, wherein the erythritol is obtained by

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grinding crystalline erythritol, it is noted that this limitation is a product-by-process limitation. As a result, a determination of patentability is only based on the product itself. Applicant is directed to MPEP 2113, which states that "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

Applicant's arguments filed 9/6/11 have been fully considered but they are not persuasive.

Applicant argues that that their independent claims recite an equation representing how much erythritol component is dissolved/undissolved in water. Applicant notes that a lack of complete dissolution of the erythritol in the composition creates an improved cooling sensation that can be experienced by a person during use. Applicant submits that Leusch requires erythritol to be dissolved since erythritol in the crystal state or particle stated cannot be absorbed into plaque. Thus, one would not have expected to achieve the objective of Leusch, which promotes uptake of non-cariogenic carbohydrate by plaque. Applicant submits a 1.132 Declaration, which shows the superior cooling properties of the instant invention in Tables 1 and 2. The Declaration shows that a representative number of different compositions conforming to Equation (1) have superior properties, while a representative number of similar compositions that do not conform to Equation (1) do not. Applicant also argues the prior

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art fails to teach that components A and B as defined by Equation (1) is a results-effective variable for obtaining any benefit. Applicant further argues that DeSadeleer cannot remedy the deficiencies in Leusch.

In response to applicant's arguments, the examiner disagrees that Leusch requires all the erythritol to be dissolved. Applicant has not pointed to any explicit teaching within the reference to show that no erythritol is present in the crystal state. Instead, applicant seems to be making mere assertions. Furthermore, the examiner directs applicant to their response dated 8/26/10 (pg. 7), where applicant admits that Leusch is silent regarding the dissolution of erythritol. Although Leusch is silent regarding the dissolution of erythritol and does not teach a composition that achieves an enhanced cooling sensation in the mouth, Leusch teaches amounts of water and erythritol that encompass and overlap with the amounts recited in the instant claims. Leusch teaches 23.56 wt.% water in Example VI and broadly discloses that 1-65 wt.% erythritol can be used in its compositions (pg. 3, lines 1-2). The examiner acknowledges that Leusch does not anticipate higher amounts of erythritol but reminds applicant that the instant rejection is made under obviousness and not anticipation. The criteria for establishing a case of prima facie obviousness is not whether the prior art exemplifies all the claimed limitations but whether the prior art suggests the claimed limitations. According to MPEP 2123, "**Disclosed examples and preferred embodiments do not constitute a teaching away from the broader disclosure** or nonpreferred embodiment." Since Leusch teaches a general range of erythritol that encompasses higher amounts of erythritol, this is sufficient in establishing obviousness. According to

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MPEP 2144.05, “[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness.” *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). An ordinary skilled artisan would be motivated to manipulate the erythritol depending on the desired properties of the composition. Burden is on applicant to prove the criticality of the erythritol amount.

Moreover, applicant’s Declaration under 37 CFR 1.132 is insufficient to overcome the rejection of the instant claims. Besides erythritol and water, it is noted that other excipients in applicant’s comparative examples were not kept constant in accordance with applicant’s working examples. For instance, the amounts of sorbitol and glycerin varied throughout both the working and comparative examples. If applicant is trying to show that the amounts of erythritol and water are critical, applicant must keep all other excipient amounts in the composition constant.

Additionally, applicant’s evidence is not commensurate in scope with the instant claims. According to MPEP 716.02, whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the “objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support.” Independent claims 1 and 2 generically recite any binder and applicant only tested sodium carboxymethylcellulose and xanthan gum. Merely showing two types of binders does not meet the larger scope of the independent claims. Furthermore, “the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range.” *In re Clemens*, 622 F.2d 1029, 1036, 206

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USPQ 289, 296 (CCPA 1980). Applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960). In this case, it is noted that applicant did not test compositions where water was added in an amount below 15 wt.% or as much as 30 wt.%. Applicant also did not test amounts of erythritol above 60 wt.% or below 10 wt.%. As such, in order to commensurate the scope of the instant claims with the alleged unexpected evidence; applicant needs to narrow the scope of the instant claims.

The examiner acknowledges applicant's arguments regarding DeSadeleer but notes that applicant's arguments regarding Leusch have been addressed above and are incorporated herein. It is noted that De Sadeleer was only cited for teaching erythritol's particle size and applicant has not argued this teaching.

As such, it is the examiner's position that the rejection over Leusch in view of DeSadeleer should be maintained for the reasons stated above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based

on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-8, 10, 13-15, 16, and 19 of copending Application No. 11/512326. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending claims are drawn to a dentrifice composition comprising 15-60 wt.% erythritol having a particle size of less than 355 um, 12-40 wt.% water, and 0.6-3 wt.% binder. The binders can be selected from sodium carboxymethylcellulose, xanthan gum, and carrageenan.

Although the copending claims do not teach the same amounts of erythritol and water as the instant claims, the copending claims recite amounts that overlap with the instant claims.

However, it would have been obvious to an artisan ordinary skill at the time the invention was made manipulate and optimize the amount of water and erythritol in the composition of the copending claims. One would have been motivated to determine the optimal amount of each ingredient in order to best achieve the desired results. It should be noted that generally difference in concentrations do not support the patentability of

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subject matter encompassed by the prior art unless there is evidence indicating such a concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding the new limitations of 13-14, wherein the erythritol is obtained by grinding crystalline erythritol, it is noted that this limitation is a product-by-process limitation. As a result, a determination of patentability is only based on the product itself. Applicant is directed to MPEP 2113, which states that "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding the instant limitations of claim 14-17 (superior cooling sensation, stability, shape, and applicability), it is the position of the examiner that these characteristics are intrinsic properties of the copending claims since the claims suggest the same components as the instant application including the erythritol, water, and binders. According to MPEP 2112.02, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

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Regarding the instant limitations of claims 6-8, wherein the composition has a viscosity at 25°C from 1500-5000 dPas, it is the examiner's position that this would be an intrinsic property of the composition taught by Leusch et al and De Sadeleer et al because the prior art suggests the same components as the instant application including erythritol, water, and binders. See *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Furthermore, as evidenced by the instant specification, a binder content exceeding 3 wt.% has an unduly high viscosity (see paragraph 0014). Since the copending claims recite the instant binder amount; it is assumed that the composition of the copending claims would not have an unduly high viscosity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant notes that the present application was filed earlier than the copending application. As such, applicant requests the examiner to withdraw the rejection.

However, the examiner respectfully disagrees with applicant that the provisional rejection should be withdrawn. According to MPEP 804, the examiner should only withdraw a provisional double patenting rejection over a later filed copending application when it is the only the rejection remaining before allowability. In this case, claims 1-17 are still rejected over prior art in addition to provisional double patenting.

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As such, it is the examiner's position that the double patenting rejection should be maintained for the reasons stated above.

Conclusion

Claims 1-17 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL WELTER whose telephone number is (571)270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611